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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,669	12/24/1999	JOHN P. ANDERSON	00228-US-NEW	7795
20350	7590	03/01/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			WALICKA, MALGORZATA A	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/471,669	ANDERSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 12/06/05.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 48,51-69 and 114-390 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 48, 51-69, and; 114-390 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/06/05 &amp; 12/08/04</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

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A Petition to Withdraw Application from Issuance Pursuant to 37 CFR

§1.31(c)(2), Request for Continued Examination under 37CFR1.114, including the fee set forth in 37 CFR 1.17(e), Amendment and Information Disclosure Statement were filed in this application on December 6, 2004. The application has been withdrawn from issuance and the prosecution is reopen.

Claims 49-50, and 70-113 have been canceled and new claims 114-390 have been added. Claims 48, 51, 58, 62 and 69 have been amended. Claims 48, 51-69, and 114-390 are pending and under examination.

**Detailed Office Action**

**1. Objections**

The newly submitted claims are numbered incorrectly; claims 126-390 should be 125-389.

**2. Rejections**

***2.1. 35 U.S.C. 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 48, 114, 122, 131, 139, 147, 155, 163 and 171 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims

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are confusing in reciting the limitation "comprising a sequence of nucleotides that encodes SEQ ID NO: X or a complementary sequence of any of such nucleotides." For examination purposes it is assumed that applicants claim an isolated nucleic acid comprising a sequence that encodes SEQ ID NO: X or comprising a sequence complementary to the encoding sequence.

Dependent claims 51-57, 115-121, 123-130, 132-138, 140-146, 148-154, 156-162, 164-170, 172-178 are included in the rejection because they do not correct the language of the claims from which they depend.

## **2.2. 35 U.S.C. 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

DNA comprising a sequence that encodes SEQ ID NO: 43

Claims 48 and 51-57, are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,420,534, issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 (see SEQ ID NO: 5). As this benefit of the filing date of the '594 provisional application is necessary for Gurney et al. to qualify as prior art under 102(e), the rejection is explained with reference to the provisional application.

The claims are directed to

an isolated nucleic acid molecule (claim 48),

expression vector (claims 51-53), and

host cell (claims 53-57),

wherein the nucleic acid molecule comprises a sequence of nucleotides encoding a truncated form of human beta secretase of SEQ ID NO: 2 (amino acid residues 46-501) identified by SEQ ID NO: 43.

The provisional application '594 discloses DNA of SEQ ID NO: 5 encoding human beta-secretase (ASP2) of SEQ ID NO: 6 (renamed as SEQ ID NO: 4 in the patent), which is identical to SEQ ID NO: 2 of the instant application. SEQ ID NO: 5 of '594 comprises any DNA molecule that encodes a truncated form of SEQ ID NO: 2 of the instant application, thus it comprises the sequence encoding SEQ ID NO: 43.

'594 discloses also expression of ASP2 in heterologous cells which are bacterial, insect, yeast or mammalian cells; see Example 4, line 15, and specification page 10 line 23, page 11 line 1 and page 11 line 18. '594 teaches also expression vectors useful for transformation; see page 9, line 11, page 10 line 28 and page 11 line 24.

In summary '594 anticipates all what is claimed in claims 48 and 51-57.

**PLEASE NOTE that claims 58-69 are not rejected under 35 USC section 102 or 35 USC section 103, because**

- 1) it is understood that the language of independent claim 58 "a vector comprising a sequence of nucleotides that encodes SEQ ID NO: 43" means that the vector comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 43 and the stop codon immediately after the translated sequence.
- 2) it is understood that the language of independent claim 64 "a heterologous cell comprising a nucleic acid molecule encoding SEQ ID NO:43" means that the heterogenous cell comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 43 and the stop codon immediately after the translated sequence.

The examiner suggests amending the claims accordingly.

DNA comprising a sequence that encodes SEQ ID NO: 58

Claims 114-121 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,420,534, issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 (see SEQ ID NO: 5). As this benefit of the filing date of the '594 provisional application is necessary for Gurney et al. to qualify as prior art under 102(e), the rejection is explained with reference to the provisional application.

The claims are directed to

an isolated nucleic acid molecule (claim 114),

expression vector (claims 115-116), and

host cell (claims 117-121),

wherein the nucleic acid molecule comprises a sequence of nucleotides encoding a truncated form of human beta secretase of SEQ ID NO: 2 (amino acid residues 46-452) identified by SEQ ID NO: 58.

The provisional application '594 discloses DNA of SEQ ID NO: 5 encoding human beta-secretase (ASP2) of SEQ ID NO: 6 (renamed as SEQ ID NO: 4 in the patent), which is identical to SEQ ID NO: 2 of the instant application. SEQ ID NO: 5 of '594 comprises any DNA molecule that encodes a truncated form of SEQ ID NO: 2 of the instant application, thus it comprises the sequence encoding SEQ ID NO: 58

'594 discloses also expression of ASP2 in heterologous cells which are bacterial, insect, yeast or mammalian cells; see Example 4, line 15, and specification page 10 line 23, page 11 line 1 and page 11 line 18. '594 teaches also expression vectors useful for transformation; see page 9, line 11, page 10 line 28 and page 11 line 24.

In summary '594 anticipates all what is claimed in claims 114 and 115-121.

**PLEASE NOTE that claims 179-184 and 241-259 are not rejected under 35 USC section 102 or 35 USC section 103, because**

- 1) **it is understood that the language of independent claim 179 "a vector comprising a sequence of nucleotides that encodes SEQ ID NO: 58" means that the vector comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 58 and the stop codon immediately after the translated sequence.**
- 2) **it is understood that the language of independent claim 241 "a heterologous cell comprising a nucleic acid molecule encoding SEQ ID NO: 58" means that the heterogenous cell comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 58 and the stop codon immediately after the translated sequence.**

**The examiner suggests amending the claims accordingly.**

**DNA comprising a sequence that encodes SEQ ID NO: 59**

**Claims 122-130 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,420,534, issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 (see SEQ ID NO: 5). As this benefit of the filing**

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date of the '594 provisional application is necessary for Gurney et al. to qualify as prior art under 102(e), the rejection is explained with reference to the provisional application.

The claims are directed to

an isolated nucleic acid molecule (claim 122),

expression vector (claims 123-124), and

host cell (claims 126-130),

wherein the nucleic acid molecule comprises a sequence of nucleotides encoding a truncated form of human beta secretase of SEQ ID NO: 2 (amino acid residues 1-452) identified by SEQ ID NO: 59.

The provisional application '594 discloses DNA of SEQ ID NO: 5 encoding human beta-secretase (ASP2) of SEQ ID NO: 6 (renamed as SEQ ID NO: 4 in the patent), which is identical to SEQ ID NO: 2 of the instant application. SEQ ID NO: 5 of '594 comprises any DNA molecule that encodes a truncated form of SEQ ID NO: 2 of the instant application, thus it comprises the sequence encoding SEQ ID NO: 59

'594 discloses also expression of ASP2 in heterologous cells which are bacterial, insect, yeast or mammalian cells; see Example 4, line 15, and specification page 10 line 23, page 11 line 1 and page 11 line 18. '594 teaches also expression vectors useful for transformation; see page 9, line 11, page 10 line 28 and page 11 line 24.

In summary, '594 anticipates all what is claimed in claims 122-130.

**PLEASE NOTE that claims 185-190 and 260-278 are not rejected under 35 USC section 102 or 35 USC section 103, because**

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- "a
- 1) it is understood that the language of independent claim 185 "vector comprising a sequence of nucleotides that encodes SEQ ID NO: 59" means that the vector comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 59 and the stop codon immediately after the translated sequence.
  - 2) it is understood that the language of independent claim 260 "a heterologous cell comprising a nucleic acid molecule encoding SEQ ID NO:59" means that the heterogenous cell comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 59 and the stop codon immediately after the translated sequence.

**The examiner suggests amending the claims accordingly.**

**DNA comprising a sequence that encodes SEQ ID NO: 66**

Claims 131-138 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,420,534, issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 (see SEQ ID NO: 5). As this benefit of the filing date of the '594 provisional application is necessary for Gurney et al. to qualify as prior art under 102(e), the rejection is explained with reference to the provisional application.

The claims are directed to

an isolated nucleic acid molecule (claim 131),

expression vector (claims 132-133), and

host cell (claims 134-138),

wherein the nucleic acid molecule comprises a sequence of nucleotides encoding a truncated form of human beta secretase of SEQ ID NO: 2 (amino acid residues 22-501) identified by SEQ ID NO: 66.

The provisional application '594 discloses DNA of SEQ ID NO: 5 encoding human beta-secretase (ASP2) of SEQ ID NO: 6 (renamed as SEQ ID NO: 4 in the patent), which is identical to SEQ ID NO: 2 of the instant application. SEQ ID NO: 5 of '594 comprises any DNA molecule that encodes a truncated form of SEQ ID NO: 2 of the instant application, thus it comprises the sequence encoding SEQ ID NO: 66.

'594 discloses also expression of ASP2 in heterologous cells which are bacterial, insect, yeast or mammalian cells; see Example 4, line 15, and specification page 10 line 23, page 11 line 1 and page 11 line 18. '594 teaches also expression vectors useful for transformation; see page 9, line 11, page 10 line 28 and page 11 line 24.

In summary, '594 anticipates all what is claimed in claims 131-138.

**PLEASE NOTE that claims 191-196 and 279-297 are not rejected under 35 USC section 102 or 35 USC section 103, because**

- 1) **it is understood that the language of independent claim 191 "vector comprising a sequence of nucleotides that encodes SEQ ID NO: 66" means that the vector comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide**

**sequence translated from amino acid sequence of SEQ ID NO: 66 and the stop codon immediately after the translated sequence.**

- 2) **it is understood that the language of independent claim 279 “a heterologous cell comprising a nucleic acid molecule encoding SEQ ID NO: 66” means that the heterogenous cell comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 66 and the stop codon immediately after the translated sequence.**

**The examiner suggests amending the claims accordingly.**

**DNA comprising a sequence that encodes SEQ ID NO: 67**

Claims 139-146 are rejected under 35 USC 102(e) as being anticipated by US Patent 6,420,534, issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 (see SEQ ID NO: 5). As this benefit of the filing date of the '594 provisional application is necessary for Gurney et al. to qualify as prior art under 102(e), the rejection is explained with reference to the provisional application.

The claims are directed to

an isolated nucleic acid molecule (claim 139),

expression vector (claims 140-141), and

host cell (claims 142-146),

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wherein the nucleic acid molecule comprises a sequence of nucleotides encoding a truncated form of human beta secretase of SEQ ID NO: 2 (amino acid residues 58-51) identified by SEQ ID NO: 67.

The provisional application '594 discloses DNA of SEQ ID NO: 5 encoding human beta-secretase (ASP2) of SEQ ID NO: 6 (renamed as SEQ ID NO: 4 in the patent), which is identical to SEQ ID NO: 2 of the instant application. SEQ ID NO: 5 of '594 comprises any DNA molecule that encodes a truncated form of SEQ ID NO: 2 of the instant application, thus it comprises the sequence encoding SEQ ID NO: 67.

'594 discloses also expression of ASP2 in heterologous cells which are bacterial, insect, yeast or mammalian cells; see Example 4, line 15, and specification page 10 line 23, page 11 line 1 and page 11 line 18. '594 teaches also expression vectors useful for transformation; see page 9, line 11, page 10 line 28 and page 11 line 24.

In summary, '594 anticipates all what is claimed in claims 139-146.

**PLEASE NOTE that claims 197--202 and 298-314 are not rejected under 35 USC section 102 or 35 USC section 103, because**

- 1) **it is understood that the language of independent claim 197 vector comprising a sequence of nucleotides that encodes SEQ ID NO: 67" means that the vector comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 67 and the stop codon immediately after the translated sequence.**

2) it is understood that the language of independent claim 298 "a heterologous cell comprising a nucleic acid molecule encoding SEQ ID NO: 67" means that the heterogenous cell comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 67 and the stop codon immediately after the translated sequence.

The examiner suggests amending the claims accordingly.

DNA comprising a sequence that encodes SEQ ID NO: 68

Claims 147-154 are rejected under 35 USC 102(e) as being anticipated by US Patent 6,420,534, issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 (see SEQ ID NO: 5). As this benefit of the filing date of the '594 provisional application is necessary for Gurney et al. to qualify as prior art under 102(e), the rejection is explained with reference to the provisional application.

The claims are directed to

an isolated nucleic acid molecule (claim 147),

expression vector (claims 148-149), and

host cell (claims 150-154),

wherein the nucleic acid molecule comprises a sequence of nucleotides encoding a truncated form of human beta secretase of SEQ ID NO: 2 (amino acid residues 68-452) identified by SEQ ID NO: 68.

The provisional application '594 discloses DNA of SEQ ID NO: 5 encoding human beta-secretase (ASP2) of SEQ ID NO: 6 (renamed as SEQ ID NO: 4 in the patent), which is identical to SEQ ID NO: 2 of the instant application. SEQ ID NO: 5 of '594 comprises any DNA molecule that encodes a truncated form of SEQ ID NO: 2 of the instant application, thus it comprises the sequence encoding SEQ ID NO: 68.

'594 discloses also expression of ASP2 in heterologous cells which are bacterial, insect, yeast or mammalian cells; see Example 4, line 15, and specification page 10 line 23, page 11 line 1 and page 11 line 18. '594 teaches also expression vectors useful for transformation; see page 9, line 11, page 10 line 28 and page 11 line 24.

In summary, '594 anticipates all what is claimed in claims 147-154.

**PLEASE NOTE that claims 203-208 and 315-333 are not rejected under 35 USC section 102 or 35 USC section 103, because**

- 1) **it is understood that the language of independent claim 203 vector comprising a sequence of nucleotides that encodes SEQ ID NO: 68“ means that the vector comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 68 and the stop codon immediately after the translated sequence.**
- 2) **it is understood that the language of independent claim 315 “a heterologous cell comprising a nucleic acid molecule encoding SEQ ID NO: 68” means that the heterogenous cell comprises the nucleotides sequence consisting of the start codon before the first**

**codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 68 and the stop codon immediately after the translated sequence.**

**The examiner suggests amending the claims accordingly.**

**DNA comprising a sequence that encodes SEQ ID NO: 69**

Claims 155-162 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,420,534, issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 (see SEQ ID NO: 5). As this benefit of the filing date of the '594 provisional application is necessary for Gurney et al. to qualify as prior art under 102(e), the rejection is explained with reference to the provisional application.

The claims are directed to

an isolated nucleic acid molecule (claim 155),

expression vector (claims 156-157), and

host cell (claims 158-162),

wherein the nucleic acid molecule comprises a sequence of nucleotides encoding a truncated form of human beta secretase of SEQ ID NO: 2 (amino acid residues 68-501) identified by SEQ ID NO: 69.

The provisional application '594 discloses DNA of SEQ ID NO: 5 encoding human beta-secretase (ASP2) of SEQ ID NO: 6 (renamed as SEQ ID NO: 4 in the patent), which is identical to SEQ ID NO: 2 of the instant application. SEQ ID NO: 5 of

'594 comprises any DNA molecule that encodes a truncated form of SEQ ID NO: 2 of the instant application, thus it comprises the sequence encoding SEQ ID NO: 69.

'594 discloses also expression of ASP2 in heterologous cells which are bacterial, insect, yeast or mammalian cells; see Example 4, line 15, and specification page 10 line 23, page 11 line 1 and page 11 line 18. '594 teaches also expression vectors useful for transformation; see page 9, line 11, page 10 line 28 and page 11 line 24.

In summary, '594 anticipates all what is claimed in claims 155-162

**PLEASE NOTE that claims 209-214 and 334-352 are not rejected under 35 USC section 102 or 35 USC section 103, because**

- 1) **it is understood that the language of independent claim 209 "vector comprising a sequence of nucleotides that encodes SEQ ID NO: 69" means that the vector comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 69 and the stop codon immediately after the translated sequence.**
- 2) **it is understood that the language of independent claim 334 "a heterologous cell comprising a nucleic acid molecule encoding SEQ ID NO: 69" means that the heterogenous cell comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 69 and the stop codon immediately after the translated sequence.**

**The examiner suggests amending the claims accordingly.**

**DNA comprising a sequence that encodes SEQ ID NO: 70**

Claims 163-170 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,420,534, issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 (see SEQ ID NO: 5). As this benefit of the filing date of the '594 provisional application is necessary for Gurney et al. to qualify as prior art under 102(e), the rejection is explained with reference to the provisional application.

The claims are directed to

an isolated nucleic acid molecule (claim 163),

expression vector (claims 164-165), and

host cell (claims 166-170),

wherein the nucleic acid molecule comprises a sequence of nucleotides encoding a truncated form of human beta secretase of SEQ ID NO: 2 (amino acid residues 63-452) identified by SEQ ID NO: 70

The provisional application '594 discloses DNA of SEQ ID NO: 5 encoding human beta-secretase (ASP2) of SEQ ID NO: 6 (renamed as SEQ ID NO: 4 in the patent), which is identical to SEQ ID NO: 2 of the instant application. SEQ ID NO: 5 of '594 comprises any DNA molecule that encodes a truncated form of SEQ ID NO: 2 of the instant application, thus it comprises the sequence encoding SEQ ID NO: 70.

'594 discloses also expression of ASP2 in heterologous cells which are bacterial, insect, yeast or mammalian cells; see Example 4, line 15, and specification page 10 line

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23, page 11 line 1 and page 11 line 18. '594 teaches also expression vectors useful for transformation; see page 9, line 11, page 10 line 28 and page 11 line 24.

In summary, '594 anticipates all what is claimed in claims 163-170.

**PLEASE NOTE that claims 215-220 and 353-371 are not rejected under 35 USC section 102 or 35 USC section 103, because**

- 1) it is understood that the language of independent claim 215 "a vector comprising a sequence of nucleotides that encodes SEQ ID NO: 70" means that the vector comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 70 and the stop codon immediately after the translated sequence.
- 2) it is understood that the language of independent claim 353 "a heterologous cell comprising a nucleic acid molecule encoding SEQ ID NO: 70" means that the heterogenous cell comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 70 and the stop codon immediately after the translated sequence.

The examiner suggests amending the claims accordingly.

DNA comprising a sequence that encodes SEQ ID NO: 74

Claims 171-178 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,420,534, issued to Gurney et al., with priority to the provisional application 60/101,594 ('594) filed Sept. 24, 1998 (see SEQ ID NO: 5). As this benefit of the filing date of the '594 provisional application is necessary for Gurney et al. to qualify as prior art under 102(e), the rejection is explained with reference to the provisional application.

The claims are directed to

an isolated nucleic acid molecule (claim 171),

expression vector (claims 172-173), and

host cell (claims 174-178),

wherein the nucleic acid molecule comprises a sequence of nucleotides encoding a truncated form of human beta secretase of SEQ ID NO: 2 (amino acid residues 22-452) identified by SEQ ID NO: 74

The provisional application '594 discloses DNA of SEQ ID NO: 5 encoding human beta-secretase (ASP2) of SEQ ID NO: 6 (renamed as SEQ ID NO: 4 in the patent), which is identical to SEQ ID NO: 2 of the instant application. SEQ ID NO: 5 of '594 comprises any DNA molecule that encodes a truncated form of SEQ ID NO: 2 of the instant application, thus it comprises the sequence encoding SEQ ID NO: 74.

'594 discloses also expression of ASP2 in heterologous cells which are bacterial, insect, yeast or mammalian cells; see Example 4, line 15, and specification page 10 line 23, page 11 line 1 and page 11 line 18. '594 teaches also expression vectors useful for transformation; see page 9, line 11, page 10 line 28 and page 11 line 24.

In summary, '594 anticipates all what is claimed in claims 171-178.

**PLEASE NOTE that claims 221-226 and 372-390 are not rejected under 35 USC section 102 or 35 USC section 103, because**

- 1) it is understood that the language of independent claim 221 "vector comprising a sequence of nucleotides that encodes SEQ ID NO: 74" means that the vector comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 74 and the stop codon immediately after the translated sequence.
- 2) it is understood that the language of independent claim 372 "a heterologous cell comprising a nucleic acid molecule encoding SEQ ID NO: 74" means that the heterogenous cell comprises the nucleotides sequence consisting of the start codon before the first codon of the nucleotide sequence translated from amino acid sequence of SEQ ID NO: 74 and the stop codon immediately after the translated sequence.

The examiner suggests amending the claims accordingly.

#### **2.4. 35 USC, first paragraph**

Claim 63, 184, 190, 196, 202, 208, 214, 220 and 226 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to the use of antibodies that bind truncated forms of beta-secretase set forth in SEQ ID NO:2. The disclosure fails to teach how to obtain and antibody that is specific for a truncated form of SEQ ID NO: 2 and lacks significant immunoreactivity to SEQ ID NO:2. One of ordinary skills in the art realizes that antibody that binds a truncated form of SEQ ID NO:2 will also bind SEQ ID NO:2. Thus, claims 63, 184, 190, 196, 202, 208, 214, 220 and 226 are rejected for lack of enablement.

## **2.5. Double patenting rejection**

### Provisional obviousness type double patenting rejection

The amended and new claims 48, 51-69, and 114-390 are rejected as anticipating genera of isolated nucleic acid, expression vectors, host cells, and methods of recombinant production and purification of beta-secretase enzymes claimed in claims 56, 61-77 of US patent application No. 09/724,569 ('569).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Provisional statutory double patenting rejection

Claim 114, 48, 131, and 171 are provisionally rejected as claiming the same invention as claims 57-60 of the US application No. 09/724,569. The claims are directed to an isolated nucleic acid that comprise or have (both transitional phrases have the same meaning) the sequence encoding amino acid sequence of SEQ ID NO: 58, 43, 66 and 74.

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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